Highly Confidential—Subject to Protective Order

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC. *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 09-037 (RBK)(JS)
	)	CONSOLIDATED
LUPIN LTD., *et al.*,	)	
	)	
Defendants.	)	
	)	
SHIONOGI PHARMA, INC., *et al.*,	)	
	)	
Plaintiffs,	)	
v.	)	C.A. No. 10-135 (RBK)(JS)
	)	
MYLAN, INC., *et al.*,	)	
	)	
Defendants.	)	REDACTED VERSION

DECLARATION OF IVAN T. HOFMANN, CPA/CFF, CLP

1. I am a Managing Director of Gleason IP, a division of Gleason & Associates, P.C. ("Gleason"). Gleason is an accounting, financial, and economic consulting firm which provides services primarily in the areas of Valuation, Litigation Support, Intellectual Property, Forensic Accounting, and Financial Reorganization.

2. I have extensive knowledge and experience in the areas of economic and market analysis in patent litigation and other areas. My intellectual property experience includes calculating damages associated with patent infringement and other intellectual property, as well as valuing intellectual property, analyzing secondary considerations of nonobviousness, and performing market analysis involving success drivers. I have extensive experience in the pharmaceutical industry and in analyzing the competition among branded and generic companies. I have been involved on the issue of damages in patent infringement cases in the pharmaceutical industry on more than 75 projects. I and others at my firm have provided expert testimony in patent infringement cases for both the pharmaceutical industry and other industries on numerous occasions.

3. I prepared a declaration dated October 19, 2011 in connection with this patent infringement case which contains additional information regarding my qualifications and experience. An updated version of my curriculum vitae and an updated listing of cases in which I have testified as an expert in the past four years are attached as Appendices to this declaration.

4. I have been informed by Kelley Drye & Warren LLP, counsel to Lupin LTD. ("Lupin"), that the Plaintiffs in this matter have served requests for the production of documents on Lupin requesting a variety of information related to highly confidential materials, including

but not limited to, Lupin's customer pricing, profitability, quantities and certain marketing information regarding its metformin hydrochloride extended release product. I understand that Lupin has objected to a number of the Plaintiffs' requests and that Plaintiffs have claimed this information is necessary in order to calculate damages allegedly incurred by the Plaintiffs.

5. I have reviewed the Declaration of Christopher P. Gerardi, dated March 30, 2012, which was filed on behalf of the Plaintiffs ("Gerardi Declaration"). The Gerardi Declaration [redacted] I have been asked by counsel for Lupin to prepare this declaration and provide opinions as to whether the documents identified in the Gerardi Declaration are relevant and/or necessary to the determination of damages in this case. I have also reviewed the declarations of Deanne Melloy and Christopher Vellturo, with associated exhibits, submitted in support of plaintiff Shionogi's motion for a preliminary injunction, and the declarations of Robert Hoffman submitted in opposition to that motion and in opposition to Shionogi's motion to compel production of commercially sensitive information.

6. This declaration addresses the unique aspects of the branded and generic pharmaceutical industry and Abbreviated New Drug Application ("ANDA") patent infringement litigation. The dynamic of competition among branded and generic companies and the competition among generic companies results in heightened commercial sensitivity of highly confidential information. The complexity and sensitivity is pronounced in this litigation given that one of the Plaintiffs (Watson) has recently launched a competitive authorized generic metformin hydrochloride extended release and one of the co-defendants (Mylan) may launch an

additional generic metformin hydrochloride extended release product in July. The Gerardi Declaration [redacted][1]

Failure to Consider the Market for Prescription Pharmaceuticals

7. I disagree with the opinions contained in the Gerardi Declaration. Based on my experience in general and in the calculation of damages in pharmaceutical patent infringement cases in particular, [redacted] Pharmaceutical patent infringement matters are impacted by the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act"). The Gerardi Declaration [redacted] The Gerardi Declaration [redacted]

[1] This declaration does not contain my opinions regarding the damages in this case if there is a finding of liability. If asked, I expect to analyze damages in a subsequent expert report which will contain my analysis regarding the appropriate form and quantum of damages assuming a finding of liability in this matter. Nothing in this declaration should be construed as an admission of acknowledgement of any particular damages remedy being appropriate at this time.

[redacted]

8. In patent infringement cases, issues may arise as to whether the patent holder would have made the sale of the product made by the alleged infringer. Issues may also arise as to whether customers would have purchased the patent holder's product in lieu of the alleged infringing product if the alleged infringing product were not on the market. In such cases, differences may exist between the patent holder's product and the allegedly infringing product that may be relevant to purchasers of the accused product and the determination of damages.

9. Unlike other patent infringement cases where consumers make purchasing decisions on whether to purchase the patented product or the accused product, demand for pharmaceutical products comes from prescriptions written by physicians. Prescription writing behavior can be influenced by many factors including promotion of branded products, prior experience with a particular drug, journal articles, studies, the availability of generics, formulary coverage, etc.[2] [redacted]

10. Sales of a generic pharmaceutical product are generated either by a physician writing a prescription for a branded reference product and the prescription being filled with a generic version of the branded reference product or a physician writing a prescription for the generic compound itself. Patient co-pays are typically lower for generic products. Therefore, the availability of a generic version of a product can influence prescribing behavior.[3] Most states

[2] Follow the Pill: Understanding the US Commercial Pharmaceutical Supply Chain," The Health Strategies Consultancy LLC, March 2005

[3] Navarro, R.P., Malone, D.C., Manieri, E., Frear, R.S., Regan, T.S., Urick, P.N, and T.J. White, 2009, "Pharmacy & Therapeutics Committees in managed care organizations," in Robert P. Navarro, ed., Managed Care Pharmacy

encourage or even require the pharmacist to substitute the generic product (if available) for the branded product.[4] Therefore, a portion of the sales made by a generic represent product that is being substituted for prescriptions written for the branded reference product.

11. The availability of generics can sometimes expand the market beyond the volume of sales the branded company would have made (i.e. if prescribing physicians begin to increase prescriptions of branded and/or generic compound due to the availability of a generic). [redacted]

[redacted]

Practice, Sudbury, Mass.: Jones and Bartlett Publishers. Also see http://www.bcbsnc.com/content/services/formulary/rxdef.htm, accessed April 18, 2012.

[4] Many states have mandatory generic substitution requirements and all states (other than Oklahoma) permit and encourage generic substitution. Pharmacies have economic incentives to substitute generic products for branded products. The Plaintiffs' prior expert acknowledged the role and impact of generic substitution. See the Declaration of Dr. Christopher A. Vellturo on behalf of Plaintiffs dated October 12, 2011, paragraph 29.

[5] Declaration of Deanne Melloy, dated October 12, 2011, paragraph 12.

[6] Declaration of Deanne Melloy, dated October 12, 2011, paragraph 12. See also my Declaration dated October 19, 2011, paragraph 24.

[redacted]

12. Given the nature of demand for prescription pharmaceuticals, much of the information requested by the Plaintiffs and referenced in the Gerardi Declaration is extraneous and unnecessary to the determination of damages.

13. The Gerardi Declaration suggests [redacted] Lost profits (if available) are calculated based on the profits of the patent holder, not the alleged infringer. I understand that disgorgement of profits of an alleged infringer is not available as a remedy in patent infringement cases. Information regarding the patent holder's profitability would come from the patent holder, not the alleged infringer. The profitability of the alleged infringer is simply not needed to analyze and quantify lost profits. [redacted]

14. The Gerardi Declaration also suggest [redacted] It is unnecessary to require the alleged infringer in a generic pharmaceutical patent infringement case to produce detailed, customer specific information regarding unit sales, pricing, discounts and rebates. As discussed more fully below, production of this unnecessary information by Lupin could have harmful consequences [redacted]

[redacted]

[9] Declaration of Christopher P. Gerardi, paragraphs 14, 18b, and 18e.
[10] Declaration of Christopher P. Gerardi, paragraphs 11, 14, 18a, and 18b.

15. The Gerardi Declaration claims [redacted]

[redacted]

[11] Declaration of Christopher P. Gerardi, paragraph 13.

[12] *Green Cross Corporation vs. Nektar Therapeutics* is a theft of trade secrets case regarding a chemical compound formulation. *Digene Corporation v. F. Hoffman La Roche LTD and Roche Molecular Systems, Inc.* is a breach of license agreement. The discovery issues in these types of cases are not relevant to this matter which involves ANDA patent infringement litigation.

[13] *Classen Immunotherapies, Inc. v. King Pharmaceutical, Inc.* is a patent infringement case, however, it is not an ANDA patent infringement litigation and does not involve branded and generic competition for FDA approved

[redacted] Price erosion damages are only potentially available if a branded company shows that price erosion has actually occurred (i.e. that the branded company actually lowered the net price on a branded product in response to generic competition).

18. In my experience, the typical response by a branded company to generic competition is to raise prices, rather than lower prices.[14] If a branded company does not lower net prices in response to generic competition, no damages in the form of price erosion exist. If a branded company raises net prices in response to generic competition, the additional profits on sales made with higher prices by the branded company may partially offset any sales potentially lost by the branded company.

19. Once again, the Gerardi Declaration [redacted]

equivalent products. Once again, the discovery issues in this type of case are not comparable to the issues identified in this ANDA patent infringement litigation.

[14] Branded companies historically recognize that they will likely lose market share to generic alternatives. However, a certain portion of the patient population is resistant to taking generic products and is willing to pay the higher price for the branded product. Given the relatively price inelastic demand for this portion of the patient population, branded companies often raise the price of the branded product following the launch of a generic version of a branded product. See Henry G. Grabowski and John M. Vernon, "Brand Loyalty, Entry, and Price Competition in

[redacted]

20. The Gerardi Declaration [redacted]

Additional Unnecessary Information Discussed in the Gerardi Declaration

21. The Gerardi Declaration [redacted]

Pharmaceuticals After the 1984 Drug Act," Journal of Law & Economics, Volume XXXV, October 1992, pp. 331-350. See also my declaration dated October 19, 2011, paragraphs 44 – 46.

[15] Fortamet®'s 2008 Business Plan SHIO019365-019387 at SHIO019367.

[16] Exhibit A to the Declaration of Robert G. Hoffman, dated October 19, 2011. Although no generic Fortamet® product was previously available, many other branded metformin products have generic alternatives (i.e. Glucophage, Glucophage XR, etc.). [redacted]

[redacted] The following documents and information requests are unnecessary to calculate damages in this matter:

- Lupin's metformin hydrochloride extended release sales channels and customer specific information such as units, pricing and discounts to each customer;[17]
- Research and development by Lupin to prepare for the launch of its metformin hydrochloride extended release product;[18]

22. The Gerardi Declaration [redacted] Specific customer information is unnecessary given the nature of prescription pharmaceutical demand and generic substitution. [redacted]

23. [redacted] The end users of both branded and generic pharmaceutical products are patients. Patients receive prescriptions from their

[17] Declaration of Christopher P. Gerardi, paragraphs 11, 14, 18a, and 18b.
[18] Declaration of Christopher P. Gerardi, paragraph 18d.
[19] Declaration of Christopher P. Gerardi, paragraphs 11, 14, 18a, and 18b.

physicians for either a branded product or generic compound and the patient receives either the product for which the prescription was written or the generic product is substituted for the branded product in filling the prescription. Most prescriptions are covered by an insurance plan which requires the patient to pay a co-pay which is typically higher for a branded product than the generic alternative. Third party payers (such as insurance companies, medicare, etc.) pay the pharmacy an amount in addition to the patient co-pay made for each prescription filled for a particular product.

24. There are tens of thousands of retail pharmacies in the United States.[21] Hospitals, medical centers, and other healthcare facilities also have pharmacies. In addition to brick and mortar pharmacies, many patients obtain prescriptions through mail order pharmacies (such as Caremark and Express Scripts). Pharmacies obtain prescription pharmaceuticals from a combination of wholesalers, distributors and/or directly from pharmaceutical companies. Wholesalers, distributors, retail pharmacies, and mail order companies purchase pharmaceutical products from companies such as the Plaintiffs and Lupin. The complex sales and distribution network through which pharmaceutical products get from the manufacturer to pharmacy shelves varies widely by company.

25. In fact, branded and generic pharmaceutical companies have different customers and distribution networks. While branded and generic pharmaceutical companies may sell their products to different networks of distributors, wholesalers and retailers, the branded or generic product is ultimately provided to the same end user (i.e. a patient with a prescription).

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[20] Declaration of Christopher P. Gerardi paragraph 11.

[21] The National Association of Chain Drug Stores ("NACDS") states that there are over 39,000 chain drug stores alone. This figure does not include independent drug stores, hospital pharmacies or mail order pharmacies.

Prescriptions written for a generic compound are filled with the generic product. Prescriptions written for a branded product are often filled with a generic product if available. As discussed above, most states encourage or require that prescriptions for branded pharmaceutical products be filled with a generic alternative, if available. Therefore, information regarding the customer, price to the customer, and/or any discounts to a particular customer is unnecessary. The Gerardi Declaration [redacted]

26. When the Gerardi Declaration [redacted] As discussed above, demand for generic pharmaceutical products comes from prescriptions being written by a physician. The Gerardi Declaration [redacted]

27. The Gerardi Declaration [redacted]

Obtained from http://www.nacds.org/user-assets/pdfs/2011/PrinciplesOfHealthcare.pdf (accessed on April 12, 2012).

[redacted] I understand that Lupin has already produced all information and documents regarding the development and filing of the ANDA.[23]

Harm to Lupin Regarding the Potential Disclosure of Highly Confidential Information

28. In addition to being unnecessary to calculate damages, it would be harmful to Lupin if Lupin is required to produce highly confidential information, including Lupin's price and profitability information by customer.[24] Based on my experience in the pharmaceutical industry, generic companies compete with each other vigorously on price, but they do not typically compete on price with the brand. If competitors obtain confidential pricing, discounting and marketing strategy information of Lupin, [redacted]

29. [redacted] One of the Plaintiffs in this case is the authorized generic for Fortamet® who recently launched a generic metformin hydrochloride extended release product. In my opinion, the requested highly confidential customer information regarding Lupin's customer pricing, profitability and marketing strategy are unnecessary to quantify alleged damages. The

[22] Declaration of Christopher P. Gerardi, paragraph 18d.
[23] See Lupin Defendant's Objections and Responses to Shionogi's Second Set of Requests for the Production of Documents and Things, dated March 15, 2012.
[24] Declaration of Robert G. Hoffman dated October 20, 2011.
[25] This court has recognized the potential harm to Lupin if highly confidential information escapes the protective order. See October 20, 2011 Hearing Transcript at 18.3-18.8.

potential disclosure of this highly confidential information to competitors could have a significant and broad negative impact on Lupin. While I understand that a protective order is in place which is intended to protect the improper disclosure of this highly confidential information, the disclosure of this information (inadvertently or in the course of this matter potentially going to trial) would be extremely harmful to Lupin. The risks associated with disclosure of this information are heightened given the launch by Watson of an authorized generic and the potential launch by Mylan in July. The risk of potential harm should be avoided given that the highly confidential information is unnecessary to determine damages.

30. As described above, damages analysis can be undertaken without profitability information for Lupin's metformin hydrochloride extended release product. Lost profits (if available) are calculated by using the profitability of the patent holder, not Lupin. As discussed more fully below, the disclosure of profitability for use in the determination of a reasonable royalty calculation is also unnecessary.

[redacted]

31. The Gerardi Declaration [redacted]

[redacted] In patent infringement cases in general, analysis of the demand for a patented product is often part of a lost profits analysis according to *Panduit* Factor number one. However, in the prescription pharmaceutical industry demand for the patented product is evidenced by sales of the brand and generic products. The FDA regulatory scheme prevents anyone else from selling the patented product through the NDA and ANDA approval process. Physicians write prescriptions for the brand product or generic compound and pharmacies fill these prescriptions with either brand or generic product. [redacted]

[26] Declaration of Christopher P. Gerardi, paragraph 14. I understand that Lupin has agreed to produce certain information regarding market analysis and forecasts for the market for generic Fortamet®. See the Response to the Request for Production 43 in the Lupin Defendants' Objections and Responses to Shionogi's Second Set of Requests for the Production of Documents and Things dated March 15, 2012.

[27] Declaration of Christopher P. Gerardi, paragraphs 15, 17, 18a, 18c, and 18e [redacted]

[28] Declaration of Christopher P. Gerardi, paragraph 14.

[29] Declaration of Christopher P. Gerardi, paragraph 11.

33. The Gerardi Declaration [redacted] Although analysis of competitors and market share may sometimes be relevant to determine lost profits using the market share approach or identifying the availability of acceptable non-infringing alternatives according to *Panduit* Factor number two, this information is not necessary for this case.[31]

34. Under the FDA regulatory framework, prescriptions written for Fortamet® can only be filled with Fortamet® or an FDA approved generic equivalent. While the metformin market had a number of generic metformin products available prior to the launch of Lupin's metformin hydrochloride extended release product, patients taking Fortamet® have physicians who chose to write prescriptions for the branded product over other available generic metformin alternatives. Patients who received Lupin's metformin hydrochloride extended release product either had physicians write a prescription for Fortamet® or the generic compound metformin hydrochloride extended release given the availability of a generic or would have otherwise taken Fortamet®.[32] [redacted]

[30] Declaration of Christopher P. Gerardi, paragraph 14.

[31] I understand that Lupin is arguing that its product does not infringe the '859 and '866 Patents. If it is determined that Lupin's product does not infringe the '859 and '866 Patents, analysis of damages is irrelevant and unnecessary. [redacted]

35. The Gerardi Declaration [redacted][33] Generic pharmaceutical companies have a different business model than branded pharmaceutical companies and typically do not expend significant dollars on marketing their products. Therefore, the requested marketing information is not needed.[34] With respect to documents related to the development, manufacturing and distribution of Lupin's metformin hydrochloride extended release products, such information is not needed to calculate alleged damages as discussed above. The Gerardi Declaration [redacted]

Determination of Reasonable Royalty

36. The Gerardi Declaration [redacted]

[33] Declaration of Christopher P. Gerardi, paragraphs 15, 17, 18a, 18c, and 18e.

[34] I understand the Lupin has agreed to produce certain marketing related information requested by the Plaintiffs (to the extent it exists). See the Response to the Request for Production 44 in the Lupin Defendants' Objections and

[redacted]

38. Once again, the Gerardi Declaration [redacted] Analysis of the profitability of the alleged infringer is sometimes used in determining a reasonable royalty rate. In particular, profitability of the alleged infringer can be relevant to determine the portion of profits attributable to the patented feature compared to other aspects of the product (i.e. in an electronic device where the patented feature is but one of many features contained in the device). The FDA regulates the sale of prescription pharmaceutical products, including the maintenance of the "Orange Book" which lists patents which purportedly cover a particular product. The hypothetical negotiation in determination of a reasonable royalty requires an assumption that the patent is valid and infringed. Given the nature of FDA regulation of prescription pharmaceuticals, a generic company would be prevented from selling a generic

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Responses to Shionogi's Second Set of Requests for the Production of Documents and Things dated March 15, 2012.

[redacted]

version of the branded product if the patents in suit are valid and infringed.[36] Therefore, profitability of the generic is not needed for analysis of apportionment to the patents in suit.

39. Profitability is also sometimes used to analyze the alleged infringer's ability to pay a royalty and maintain a reasonable profit. [redacted] Therefore, actual profitability information is unnecessary to determine the ability to pay a royalty and maintain a reasonable profit.

40. I understand that Lupin is concerned with disclosing highly confidential information to direct competitors including customer specific information regarding pricing, profitability, discounts, shipping, etc. Calculation of a reasonable royalty can be performed without the disclosure of Lupin's actual profitability (in total or by customer) for its metformin hydrochloride extended release product and should be avoided given the potential harm to Lupin.

Conclusion

41. [redacted]

[36] Given the FDA regulatory framework for prescription pharmaceutical products, the discussion of information in [redacted]

[37] See the Declaration of Robert Hoffman dated October 19, 2011, paragraphs 17 to 20. [redacted]

I, Ivan T. Hofmann, hereby declare, under penalty of perjury under 28 U.S.C. § 1746 and the laws of the United States of America, that the foregoing Declaration is true and correct.

Date: April 23, 2012

Redacted Version Filed on July 25, 2012

Ivan T. Hofmann, CPA/CFF, CLP

ITH/amm

market for metformin hydrochloride extended release. Price competition from Watson and Mylan as well as from other generic metformin hydrochloride products may also impact margins.